

Sentina® Ivory Latex

Examination Gloves Latex, non-sterile

REF 163040 - 163044

February 2025

1. Composition of the product

Sentina® Ivory Latex Examination Gloves consist of

- natural latex

Please note:

Persons who are allergic to natural latex must not use this product or must avoid direct skin contact.

The product contains dithiocarbamates - do not use in case of intolerance

Thiurams are not used as a curing agent in the production of the examination gloves.

This product data sheet covers the following items:

REF	Product Description	Size
163040	Sentina® Ivory Latex Examination Gloves, powder-free, chlorinated	XS (5-6)
163041	Sentina® Ivory Latex Examination Gloves, powder-free, chlorinated	S (6-7)
163042	Sentina® Ivory Latex Examination Gloves, powder-free, chlorinated	M (7-8)
163043	Sentina® Ivory Latex Examination Gloves, powder-free, chlorinated	L (8-9)
163044	Sentina® Ivory Latex Examination Gloves, powder-free, chlorinated	XL (9-10)

2. Packaging, structure and composition

2.1 Unit container

see 2.2

2.2 Shelf container

1 folding box consisting of cellulose

REF	Pieces
163040 - 163043	100

REF	Pieces
163044	90

2.3 Transit container

1 corrugated cardboard box consisting of cellulose

REF	Pieces	Folding Boxes
163040- 163043	1.000	10
163044	900	10

3. Manufacturer

The information about production is the responsibility of the legal manufacturer:

Sri Trang Gloves (Thailand) Public Company Limited
10 Soi 10, Phetkasem Road, Hat Yai,
Songkhla 90110
Thailand

4. Description

Sentina® Ivory Latex Examination Gloves are natural-coloured latex gloves with a rolled rim. The product is available in different sizes.

5. Properties

- Rolled cuff
- Textured at finger tip surface
- Protein content: max 50µg/g

6. Intended purpose

The Sentina® Ivory Latex Examination Glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. The glove is intended for medical activities except surgery.

7. Medical device Classification

Sentina® Ivory Latex Examination Gloves is a medical device of class I under to rule 1 and 5 according to Annex VIII (according to the Regulation (EU) 2017/745 on medical devices (MDR)).

8. Biological evaluation and biocompatibility (EN ISO 10993)

The information about biological assessment and compatibility is the responsibility of the legal manufacturer:

Sri Trang Gloves (Thailand) Public Company Limited
10 Soi 10, Phetkasem Road, Hat Yai,
Songkhla 90110
Thailand

9. Stability

Stored appropriately – keep cool and dry, protected from dust - Sentina® Ivory Latex Examination Gloves have a shelf life of 5 years from the date of manufacture.

Keep in clean, cool and dry area. Protect gloves from freezing and avoid excessive heat. Shield from direct sunlight, fluorescent lighting, x-rays, moisture and ozone.

10. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse. Packaging materials must also be disposed of in compliance with applicable national Requirements.

11. Legal manufacturer

The following legal manufacturer hereby confirms the accuracy of the information provided in this product data sheet:

Legal manufacturer:

**Sri Trang Gloves (Thailand)
Public Company Limited
10 Soi 10, Phetkasem Road, Hat Yai
Songkhla 90110
Thailand**

Distributor:

**Lohmann & Rauscher Internat
GmbH & Co. KG
Westerwaldstraße 4
56579 Rengsdorf
Germany**



Sureerat Choosri
Product Division Manager
Date: 11 February 2025



Hannah Künzel, Feb 23,2025 01:40:14 PM UTC



Daniela Mandt, Feb 24,2025 05:12:20 AM UTC

Date/Signature

EC Rep:
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